REMARKS

Upon entry of the above amendment, claims 1, 3-6 and 8 are pending in the present application.

Claim 1 has been amended, and claims 2, 7 and 9 have been canceled, for the sole reason of advancing prosecution. Applicants, by amending or cancelling any claims herein, make no admission as to the validity of any rejection made by the Examiner against any of these claims. Applicants reserve the right to reassert any of the claims canceled herein or the original claim scope of any claim amended herein, in a continuing application.

The subject matter of cancelled claim 2 has been amended into claim 1. Specifically, claim 1 has been amended to recite "a patch-containing packaging pouch comprising: a packaging pouch comprising a polyacrylonitrile layer on the innermost side; and a patch housed within the packaging pouch comprising a support and a pressure-sensitive adhesive layer is formed on one side of the support, and the pressure-sensitive adhesive layer is formed of a pressure-sensitive adhesive composition comprising a pressure-sensitive adhesive comprising at least one compound selected from the group consisting of a styrene-isoprene-styrene block copolymer, polyisobutylene and an acrylic polymer, and bisoprolol or a pharmaceutically acceptable salt thereof, present in an amount of 1 to 50% by mass in the pressure-sensitive adhesive composition, wherein relative humidity inside the packaging pouch at 25°C is maintained at 10% or less." Support for amended claim 1 can be found throughout the specification and claims as originally filed. For example, please *see* the present specification at page 14, line 10.

As the subject matter in the present pending claims does not require that the Examiner conduct a further search than that which was preformed prior to the outstanding Official Action, Applicants respectfully request that the present claims are examined on the merits without the necessity of filing a Request for Continued Examination. In this regard, should the Examiner maintain the outstanding rejections, Applicants respectfully request that the Examiner expressly address the remarks set forth herein below in an Advisory Action prior the expiration of the statutory time period set for response.

No new matter has been added.

In view of the remarks set forth herein, further and favorable consideration is respectfully requested.

I. At page 2 of the Official Action, claims 1-6 and 8 have rejected under 35 USC § 112, second paragraph.

The Examiner asserts that claims 1-6 and 8 are indefinite for reciting the phrase "a support" in line 5 of claim 1.

Applicants note that claim 2 has been cancelled without prejudice or disclaimer. Accordingly, the rejection of claim 2 has been obviated.

In view of the foregoing, Applicants respectfully traverse the rejection of claims 1, 3-6 and 8.

Applicants thank the Examiner for the pointing out the typographical error in claim 1, line 1. In particular, as suggested by the Examiner, claim 1 has been amended, at line 5, to recite the phrase "the support" in place of the phrase "a support."

In view of the foregoing, it is submitted that claims 1, 3-6 and 8 are clear and definite within the meaning of 35 USC § 112, second paragraph. Accordingly, the Examiner is respectfully requested to withdraw this rejection.

II. ***At pages 2-7 of the Official Action, claims 1-6 and 8 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Wilking (US Patent No. 5,698,217) in view of Klokkers et al. (US Patent Application Publication No. 2004/0086552), in view of Kanios et al. (US Patent No. 6,905,016) in view of Higo et al. (US Patent No. 5,866,157) in further view of Asmussen et al. (US Patent No. 6,267,982) and in further view of Takayuki et al. (Japanese Patent No. 61-73547).***

The Examiner asserts that it would have been obvious to combine the transdermal drug delivery system of Wilking with the transdermal therapeutic system containing bisoprolol as described in Klokkers et al., the acrylic polymer pressure-sensitive adhesive as described in Kanios et al., the drug content of 1 to 50% by mass as described by Higo et al., the relative humidity inside the packaging pouch of between 5% and below 0.5% as described by Asmussen et al. and the polyacrylonitrile-based resin as an innermost layer as taught by Takauki et al. to arrive at the presently claimed subject matter.

Applicants note that claim 2 has been cancelled without prejudice or disclaimer. Accordingly, the rejection of claim 2 has been obviated.

In view of the foregoing, Applicants respectfully traverse the rejection of claims 1, 3-6 and 8.

To establish a *prima facie* case of obviousness, the PTO must satisfy three requirements. First, as the U.S. Supreme Court very recently held in *KSR International Co. v. Teleflex Inc. et al.*, 550 U. S. 398 (2007), "a court must ask whether the

improvement is more than the predictable use of prior art elements according to their established functions. ...it [may] be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. ...it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does... because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." (*KSR*, 550 U.S. at 417). Second, the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. *Amgen Inc. v. Chugai Pharm. Co.*, 18 USPQ2d 1016, 1023 (Fed. Cir. 1991). Lastly, the prior art references must teach or suggest all the limitations of the claims. *In re Wilson*, 165 USPQ 494, 496 (C.C.P.A. 1970).

It is submitted that a proper case of *prima facie* obviousness has not been established because, whether taken alone or together, none of the cited references teach or suggest all the limitations of the claims as required by *In re Wilson*.

Independent claim 1 is directed to a patch-containing packaging pouch comprising: a packaging pouch comprising a polyacrylonitrile layer on the innermost side; and a patch housed within the packaging pouch comprising a support and a pressure-sensitive adhesive layer is formed on one side of the support, and the

pressure-sensitive adhesive layer is formed of a pressure-sensitive adhesive composition comprising a pressure-sensitive adhesive comprising at least one compound selected from the group consisting of a styrene-isoprene-styrene block copolymer, polyisobutylene and an acrylic polymer, and bisoprolol or a pharmaceutically acceptable salt thereof, present in an amount of 1 to 50% by mass in the pressure-sensitive adhesive composition, wherein relative humidity inside the packaging pouch at 25°C is maintained at 10% or less. Claims 3-6 and 8 all depend, either directly or indirectly, from claim 1.

In contrast to the presently claimed subject matter, Wilking describes a transdermal drug delivery device including a carrier containing a dissolved drug. According to Wilking, the device also includes a desiccant package that is inert to the carrier, permeable to water vapor, and defines a desiccant compartment containing a desiccant. Further, according to Wilking, the device also includes a water vapor impermeable product package that contains the carrier and the desiccant package. *See* Wilking at the Abstract.

However, Wilking does not teach or suggest every element of the present subject matter. Nowhere does Wilking teach or suggest, at least, "...***bisoprolol or a pharmaceutically acceptable salt thereof, present in an amount of 1 to 50% by mass in the pressure-sensitive adhesive composition***..." and that the "...***relative humidity inside the packaging pouch at 25°C is maintained at 10% or less***...", as recited in pending claim 1.

Klokkers et al. do not remedy the deficiencies of Wilking. Klokkers et al. describe a transdermal therapeutic system comprising a surface layer which is impervious with

respect to an active ingredient; a self-adherent matrix layer or a plurality of matrix layers, wherein the exposed matrix layer is self-adherent when the system is applied. According to Klokkers et al., the transdermal therapeutic system also comprises a pull-off protective coating, whereby the matrix layer(s) contain one or more active ingredients and/or one or more biologically active substances and highly dispersed silicon dioxide. *See* Klokkers et al. at the Abstract.

However, like Wilking, Klokkers et al. do not teach or suggest every element of the present subject matter. In this regard, whether taken alone or in combination neither Wilking nor Klokkers et al. teach or suggest, at least, "...***bisoprolol or a pharmaceutically acceptable salt thereof, present in an amount of 1 to 50% by mass in the pressure-sensitive adhesive composition***..." and that the "...***relative humidity inside the packaging pouch at 25°C is maintained at 10% or less***...", as recited in pending claim 1.

Kanios et al. do not remedy the deficiencies of Wilking and Klokkers et al. Kanios et al. describe a device and method for stabilizing a drug in a carrier composition of a transdermal delivery system by providing a product packaging system to prevent or control degradation reactions. *See* Kanios et al. at the Abstract.

However, like Wilking and Klokkers et al., Kanios et al. do not teach or suggest every element of the present subject matter. In this regard, whether taken alone or in combination, none of Wilking, Klokkers et al. and Kanios et al. teach or suggest, at least, "...***bisoprolol or a pharmaceutically acceptable salt thereof, present in an amount of 1 to 50% by mass in the pressure-sensitive adhesive composition***..." and that the "...***relative humidity inside the packaging pouch at 25°C is maintained***

at 10% or less...", as recited in pending claim 1.

Higo et al. do not remedy the deficiencies of Wilking, Klokkers et al., and Kanios et al. Higo et al. describe a matrix type patch formulation comprising an adhesive layer containing a physiologically active substance, an organic acid, a hydrophobic material, a tackifying resin, a plasticizer and an absorption enhancer. *See* Higo et al. at the Abstract.

However, like Wilking, Klokkers et al., and Kanios et al., Higo et al. do not teach or suggest every element of the present subject matter. In this regard, whether taken alone or in combination, none of Wilking, Klokkers et al., Kanios et al. and Higo et al. teach or suggest, at least, "...***bisoprolol or a pharmaceutically acceptable salt thereof, present in an amount of 1 to 50% by mass in the pressure-sensitive adhesive composition***..." and that the "...***relative humidity inside the packaging pouch at 25℃ is maintained at 10% or less***...", as recited in pending claim 1.

Asmussen et al. do not remedy the deficiencies of Wilking, Klokkers et al., Kanios et al., and Higo et al. Asmussen et al. describe transdermal pharmaceutical preparation for the release of the active substance 17-β-estradiol. *See* Asmussen et al. at the Abstract.

However, like Wilking, Klokkers et al., Kanios et al., and Higo et al., Asmussen et al. do not teach or suggest every element of the present subject matter. In this regard, whether taken alone or in combination, none of Wilking, Klokkers et al., Kanios et al. and Asmussmen et al. teach or suggest, at least, "...***bisoprolol or a pharmaceutically acceptable salt thereof, present in an amount of 1 to 50% by mass in the pressure-sensitive adhesive composition***..." and that the "...***relative humidity***

inside the packaging pouch at 25℃ is maintained at 10% or less...", as recited in pending claim 1.

Takayuki et al. describe "an anti-inflammatory, analgesic drug packaging body formed by affixing a peel-off protective film configured from a polyacrylonitrile-based resin on the drug-coated surface of a film-like or sheet-like anti-inflammatory, analgesic drug, and packaging and hermetically-sealing the same in a bag having an innermost layer of polyacrylonitrile-based resin which forms the innermost layer of the bag." *See* Takayuki et al. at page 2.

However, like Wilking, Klokkers et al., Kanios et al., Higo et al. and Asmussen et al., Takyuki et al. do not teach or suggest every element of the present subject matter. In this regard, whether taken alone or in combination, none of Wilking, Klokkers et al., Kanios et al., Asmussmen et al. and Takyuki et al. teach or suggest, at least, "...***bisoprolol or a pharmaceutically acceptable salt thereof, present in an amount of 1 to 50% by mass in the pressure-sensitive adhesive composition***..." and that the "...***relative humidity inside the packaging pouch at 25℃ is maintained at 10% or less***...", as recited in pending claim 1.

In view of the remarks set forth herein, it is submitted that nothing in any of the applied references, taken alone or together, renders claims 1, 3-6 and 8 obvious within the meaning of 35 USC § 103 (a). Accordingly, the Examiner is respectfully requested to withdraw this rejection.

CONCLUSION

In view of the foregoing, Applicants submit that the application is in condition for immediate allowance. Early notice to that effect is earnestly solicited. The Examiner is invited to contact the undersigned attorney if it is believed that such contact will expedite the prosecution of the application.

In the event this paper is not timely filed, Applicants petition for an appropriate extension of time. Please charge any fee deficiency or credit any overpayment to Deposit Account No. 14-0112.

Respectfully submitted,

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